

WHAT IS CLAIMED IS:

1. A planning system for planning a cryosurgical ablation procedure, comprising:

- (a) a first imaging modality for creating digitized preparatory images of an intervention site;
- (b) a three-dimensional modeler for creating a three-dimensional model of said intervention site based on said digitized preparatory images; and
- (c) a simulator for simulating a cryosurgical intervention, which comprises:
 - (i) an interface useable by an operator for specifying loci for insertion of cryoprobes and operational parameters for operation of said cryoprobes for cryoablating tissues; and
 - (ii) a displayer for displaying in a common virtual space an integrated image comprising a display of said three-dimensional model of said intervention site and a virtual display of cryoprobes inserted at said loci.

2. The planning system of claim 1, further comprising a memory for storing said specified loci for insertion of cryoprobes and said operational parameters for operation of said cryoprobes.

3. The planning system of claim 1, wherein said first imaging modality is selected from the group consisting of magnetic resonance imaging, ultrasound imaging and computerized tomography imaging.

[illegible]

4.) The planning system of claim 1, wherein said three-dimensional model is expressible in a three-dimensional Cartesian coordinate system.

5. The planning system of claim 1, wherein said interface also serves for highlighting selected regions within said three-dimensional model.

6. The planning system of claim 5, wherein said integrated image further comprises a display of an operator-highlighted regions.

7. The planning system of claim 5, wherein said interface is useable by an operator for identifying tissues to be cryoablated.

8. The planning system of claim 7, wherein said integrated image further comprises a display of said operator-identified tissues to be cryoablated.

9. The planning system of claim 5, wherein said interface is useable by an operator for identifying tissues to be protected from damage during cryoablation.

10. The planning system of claim 9, wherein said integrated image further comprises a display of said operator-identified tissues to be protected from damage during said cryoablation.

11. The system of claim 1, further comprising a predictor for predicting an effect on tissues of the patient of operation of said cryoprobes at said loci according to said operational parameters.

69

12. The system of claim 11, wherein said model displayer additionally displays in said common virtual space a representation of said predicted effect.

13. The system of claim 11, further comprising an evaluator for comparing said predicted effect to an operator-defined goal of said procedure.

14. The system of claim 13, wherein said evaluator is for identifying areas of predicted less-than-total destruction of tissues within a volume of desired total destruction of tissues as defined by an operator.

15. The system of claim 13, wherein said evaluator is for identifying areas specified as requiring protection during cryoablation which may be endangered by a specified planned cryoablation procedure.

16. The system of claim 1, further comprising a recommender for recommending cryosurgical procedures to an operator, said recommendation being based on goals of a cryoablation procedure, said goals being specified by said operator, and further being based on said three-dimensional model of said site, thereby facilitating planning the cryoablation procedure.

17. The system of claim 16, wherein said recommender recommends an optimal number of cryoprobes for use in a cryoablation procedure.

18. The system of claim 16, wherein said recommender recommends an optimal temperature for a cryoprobe for use in a cryoablation procedure.

T E C H N I C A L D I A G N O S T I C S

70

19. The system of claim 16, wherein said recommender recommends an optimal duration of cooling for a cryoprobe for use in a cryoablation procedure.

20. The system of claim 17, wherein said recommendation is based on a table of optimal interventions based on expert recommendations.

21. The system of claim 17, wherein said recommendation is based on a table of optimal interventions based on compiled feedback from a plurality of operators.

22. The system of claim 17, wherein said recommendation comprises specific locations for insertion of a cryoprobe to affect cryoablation.

23. The system of claim 16, wherein said recommended procedures are for cryoablation of tissues of a prostate.

24. The system of claim 23, wherein said recommended procedures are for treating BPH.

25. The system of claim 23, wherein said recommended procedures are for treating BPH percutaneously.

26. The system of claim 25, wherein said recommended procedures are for treating BPH transperineally.

27. The system of claim 23, wherein said recommended procedures are for treating a mass.

T01620 T132T600

71

28. The system of claim 27, wherein said recommended procedures are for treating a malignancy.

29. The system of claim 24, wherein said table comprises a measure of volume of a prostate.

30. The system of claim 24, wherein said table comprises a measure of length of a stricture of a urethra.

31. The system of claim 24, wherein said table comprises a measure of symptomatic severity of a BPH condition.

32. The system of claim 31, wherein said measure of symptomatic severity of a BPH condition is an AUA score.

33. The system of claim 27, wherein said recommendation is of multiple cryoprobes closely placed so as to ensure a continuous cold field sufficient to ensure complete destruction of tissues within a target volume, while minimizing damage to tissues outside said target volume.

34. A surgical facilitation system for facilitating a cryosurgery ablation procedure, comprising:

- (a) a first imaging modality, for creating digitized preparatory images of an intervention site;
- (b) a three-dimensional modeler for creating a first three-dimensional model of said intervention site based on said digitized preparatory images;
- (c) a second imaging modality, for creating a digitized real-time image of at least a portion of said intervention site during a cryosurgery procedure; and

72

- (d) an images integrator for integrating information from said three-dimensional model of said site and from said real-time image of said site in a common coordinate system, thereby producing an integrated image.

35. The surgical facilitation system of claim 34, further comprising a planning system according to claim 1.

36. The surgical facilitation system of claim 34, further comprising a displayer for displaying said integrated image in a common virtual space.

37. The surgical facilitation system of claim 36, wherein said displayed integrated image is a two-dimensional image.

38. The surgical facilitation system of claim 36, wherein said displayed integrated image is a three-dimensional image.

39. The surgical facilitation system of claim 34, further comprising a three-dimensional modeler for creating a second three-dimensional model of at least a portion of said intervention site based on a plurality of real-time images.

40. The surgical facilitation system of claim 39, wherein said images integrator is further operable for integrating information from said first three-dimensional model of said site and from said second three-dimensional model of at least a portion of said site in a common coordinate system.

TELETYPE UNIT

41. The surgical facilitation system of claim 34, wherein said first imaging modality comprises at least one of a group comprising magnetic resonance imaging, ultrasound imaging, and computerized tomography imaging.

42. The surgical facilitation system of claim 34, wherein said second imaging modality comprises at least one of a group comprising magnetic resonance imaging, ultrasound imaging, and computerized tomography imaging.

43. The surgical facilitation system of claim 42, wherein said second imaging modality comprises an imaging tool operable to report a position of said tool during creation of said real-time image, thereby providing localizing information about said real-time image useable by said images integrator.

44. The surgical facilitation system of claim 43, wherein said imaging tool is an ultrasound probe inserted in the rectum of a patient and operable to report a distance of penetration in the rectum of the patient during creation of ultrasound images of a prostate of the patient.

45. The surgical facilitation system of claim 34, wherein said first three-dimensional model is expressed in a three-dimensional Cartesian coordinate system.

46. The surgical facilitation system of claim 36, further comprising an interface useable by an operator for highlighting selected regions within said first three-dimensional model.

74

47. The surgical facilitation system of claim 36, wherein said integrated image further comprises a display of an operator-highlighted region.

48. The surgical facilitation system of claim 36, wherein said interface is useable by an operator for identifying tissues to be cryoablated.

49. The surgical facilitation system of claim 48, wherein said integrated image further comprises a display of said operator-identified tissues to be cryoablated.

50. The surgical facilitation system of claim 36, wherein said interface is useable by an operator for identifying tissues to be protected from damage during cryoablation.

51. The surgical facilitation system of claim 50, wherein said integrated image further comprises a display of said operator-identified tissues to be protected from damage during said cryoablation.

52. The surgical facilitation system of claim 46, wherein said interface is useable by an operator for labeling topographic features of said first three-dimensional model.

53. The surgical facilitation system of claim 46, wherein said interface is useable by an operator for labeling topographic features of said real-time images.

54. The surgical facilitation system of claim 46, wherein said interface is useable by an operator for labeling topographic features of said second three-dimensional model.

T04220-113260

55. The surgical facilitation system of claim 46, wherein said images integrator matches operator-labeled topographic features of said first three-dimensional model with operator-labeled features of said real-time images, to orient said first three-dimensional model and said real-time image with respect to said common coordinate system.

56. The surgical facilitation system of claim 39, wherein said images integrator matches operator-labeled topographic features of said first three-dimensional model with operator-labeled features of said second three-dimensional model, to orient said first three-dimensional model and second three-dimensional model with respect to said common coordinate system.

57. The surgical facilitation system of claim 36, further comprising a simulator for simulating a cryosurgical intervention, said simulator comprising an interface useable by an operator during a planning phase of said intervention, for specifying loci for insertion of cryoprobes and operational parameters for operation of said cryoprobes for cryoablating tissues, said image integrator being operable to integrate said operator-specified loci for insertion of cryoprobes into said integrated image, and said displayer being operable to display said integrated image.

58. The surgical facilitation system of claim 36, further comprising a first comparator for comparing said first three-dimensional model with said real-time image to determine differences, a representation of said differences being further displayed by said displayer in said integrated image.

59. The surgical facilitation system of claim 57, further comprising apparatus for providing feedback to an operator regarding

76

position of tools being used during a surgical intervention as compared to said loci for insertion of cryoprobes specified by an operator during said planning phase of said intervention.

60. The surgical facilitation system of claim 34, further comprising apparatus for providing feedback to an operator regarding position of tools being used during a surgical intervention as compared to operator-identified tissues to be cryoablated.

61. The surgical facilitation system of claim 34, further comprising apparatus for providing feedback to an operator regarding position of tools being used during a surgical intervention as compared to operator-identified tissues to be protected during cryoablation.

62. The surgical facilitation system of claim 57, further comprising apparatus for guiding an operator in the placement of cryoprobes for affecting cryoablation, said guiding being according to said loci for insertion of cryoprobes specified by an operating during said planning phase of said intervention.

63. The surgical facilitation system of claim 57, further comprising an apparatus for limiting movements of a cryoprobes during a cryoablation intervention according to said loci for insertion of cryoprobes specified by an operator during said planning phase of said intervention.

64. The surgical facilitation system of claim 57, further comprising a cryoprobe displacement apparatus for moving at least one cryoprobe to at least one of said loci for insertion of cryoprobes specified by an operating during said planning phase of said intervention.

65. The surgical facilitation system of claim 64, wherein said cryoprobe displacement apparatus comprises a stepper motor.

66. The surgical facilitation system of claim 64, wherein said cryoprobe displacement apparatus comprises a position sensor.

67. The surgical facilitation system of claim 64, operable to affect cooling of said at least one cryoprobe.

68. The surgical facilitation system of claim 64, operable to affect heating of said at least one cryoprobe.

69. The surgical facilitation system of claim 67, operable to affect scheduled movement of said at least one cryoprobe coordinated with scheduled alternative heating and cooling of said at least one cryoprobe, to affect cryoablation at a plurality of loci.

70. A cryoablation method for ensuring complete destruction of tissues within a selected target volume while minimizing destruction of tissues outside said selected target volume, comprising:

- (a) deploying a plurality of cryoprobes in a dense array within said target volume; and
- (b) cooling said cryoprobes to affect cryoablation, while limiting said cooling to a temperature only slightly below a temperature ensuring complete destruction of tissues, thereby limiting destructive range of each cooled cryoprobe, said plurality of cryoprobes being deployed in an array sufficiently dense to ensure destruction of tissues within said target volume.

2001 JUL 31 16:11 EHRlich & PARTNERS 972-3-6127575 NO.585 P.15

71. The cryoablation method of claim 70, further comprising utilizing a planner for planning said dense array, said planner utilizing a three-dimensional model of said target volume to calculate a required density of said dense array of deployed cryoprobes operated at a selected temperature, to affect complete destruction of tissues within said selected target volume.

72. The cryoablation method of claim 70, further comprising utilizing a planner for planning said dense array, said planner utilizing a three-dimensional model of said target volume to calculate, for a plurality of cryoprobes deployed to a selected array of freezing loci, a temperature and duration of cooling for each of said cryoprobes sufficient to affect complete destruction of tissues within said selected target volume, while also minimizing cooling of tissues outside of said selected target volume.

73. A cryoablation method ensuring complete destruction of tissues within a selected target volume while minimizing destruction of tissues outside said selected target volume, comprising:

- (a) utilizing cryoprobes to affect cryoablation at a plurality of freezing loci, said loci being of a first type and of a second type, said first type being located adjacent to a surface of said selected target volume and said second type being located at an interior portion of said selected target volume; and
- (b) cooling cryoprobes deployed at loci of said first type to a first degree of cooling and cooling cryoprobes deployed at loci of said second type to a second degree of cooling, said first degree of cooling being less cooling than said second degree of cooling, thereby affecting wide areas of destruction around each cryoprobe deployed at loci of said second type and narrow areas of destruction around each cryoprobe deployed at loci of said first type, thereby ensuring complete destruction

FOR THE "FBI" FILE

of tissues within a selected target volume while minimizing destruction of tissues outside said selected target volume .

74. The cryoablation method of claim 73, wherein cryoprobes deployed to freezing loci of said first type are cooled to a first temperature and cryoprobes deployed to freezing loci of said second type are cooled to a second temperature, said second temperature being lower than said first temperature.

75. The cryoablation method of claim 73, wherein cryoprobe deployed to freezing loci of said first type are cooled for a first length of time, and cryoprobe deployed to freezing loci of said second type are cooled for a second length of time, said second length of time being longer than said first length of time.

76. The cryoablation method of claim 73, further comprising utilizing a planner for planning said dense array, said planner utilizing a three-dimensional model of said target volume to calculate, for a given array of freezing loci, a required temperature and length of cooling time for loci of said first type and for loci of said second type, to affect complete destruction of tissues within said selected target volume while minimizing destruction of tissues outside said selected target volume.

77. A method for planning a cryosurgical ablation procedure, comprising:

- (a) utilizing a first imaging modality to create digitized preparatory images of an intervention site;
- (b) utilizing a three-dimensional modeler to create a three-dimensional model of said intervention site based on said digitized preparatory images; and

80

- (c) utilizing a simulator having an interface useable by an operator for specifying loci for insertion of cryoprobes and for specifying operational parameters for operation of said cryoprobes, to specify loci for insertion of cryoprobes and operational parameters for operation of said cryoprobes for cryoablating tissues;

thereby simulating a planned cryosurgical ablation procedure.

78. The method of claim 77, further comprising utilizing a displayer to display in a common virtual space an integrated image comprising a display of said three-dimensional model of said intervention site and a virtual display of cryoprobes inserted at said loci.

79. The method of claim 77, further comprising utilizing a memory to store said specified loci for insertion of cryoprobes and said operational parameters for operation of said cryoprobes.

80. The method of claim 77, wherein said first imaging modality is selected from the group consisting of magnetic resonance imaging, ultrasound imaging and computerized tomography imaging.

81. The method of claim 77, wherein said three-dimensional model is expressible in a three-dimensional Cartesian coordinate system.

82. The method of claim 77, further comprising utilizing said interface to highlight selected regions within said three-dimensional model.

83. The method of claim 82, further comprising utilizing said interface to identify tissues to be cryoablated.

81

84. The method of claim 78, wherein said integrated image comprises a display of said operator-identified tissues to be cryoablated.

85. The method of claim 82, further comprising utilizing said interface to identify tissues to be protected from damage during cryoablation.

86. The method of claim 78, wherein said integrated image comprises a display of operator-identified tissues to be protected from damage during cryoablation.

87. The method of claim 78, further comprising utilizing a predictor to predict an effect on tissues of the patient of operation of said cryoprobes at said loci according to said operational parameters.

88. The method of claim 87, wherein said model displayer additionally displays in said common virtual space a representation of said predicted effect.

89. The method of claim 87, further comprising utilizing an evaluator to compare said predicted effect to an operator-defined goal of said procedure.

90. The method of claim 89, further comprising utilizing said evaluator to identify areas of predicted less-than-total destruction of tissues within a volume of desired total destruction of tissues as defined by an operator.

91. The method of claim 89, further comprising utilizing said evaluator to identify areas specified as requiring protection during

TELETYPE

cryoablation which may be endangered by a specified planned cryoablation procedure.

92. The method of claim 77, further comprising utilizing a recommender for recommending cryosurgical procedures, said recommendation being based on goals of a cryoablation procedure, said goals being specified by an operator, and further being based on said three-dimensional model of said site.

93. The method of claim 92, wherein said recommender recommends an optimal number of cryoprobes for use in a cryoablation procedure.

94. The method of claim 92, wherein said recommender recommends an optimal temperature for a cryoprobe for use in a cryoablation procedure.

95. The method of claim 92, wherein said recommender recommends an optimal duration of cooling for a cryoprobe for use in a cryoablation procedure.

96. The method of claim 93, wherein said recommendation is based on a table of optimal interventions based on expert recommendations.

97. The method of claim 93, wherein said recommendation is based on a table of optimal interventions based on compiled feedback from a plurality of operators.

090734-072404
T022073404

83

98. The method of claim 93, wherein said recommendation comprises specific locations for insertion of a cryoprobe to affect cryoablation.

99. The method of claim 92, wherein said recommended procedures are for cryoablation of tissues of a prostate.

100. The method of claim 99, wherein said recommended procedures are for treating BPH.

101. The method of claim 99, wherein said recommended procedures are for treating BPH percutaneously.

102. The method of claim 101, wherein said recommended procedures are for treating BPH transperineally.

103. The method of claim 99, wherein said recommended procedures are for treating a mass.

104. The method of claim 103, wherein said recommended procedures are for treating a malignancy.

105. The method of claim 100, wherein said table comprises a measure of volume of a prostate.

106. The method of claim 100, wherein said table comprises a measure of length of a stricture of a urethra.

107. The method of claim 100, wherein said table comprises a measure of symptomatic severity of a BPH condition.

T0320"07204

108. The method of claim 107, wherein said measure of symptomatic severity of a BPH condition is an AUA score.

109. The method of claim 103, wherein said recommendation is of multiple cryoprobes closely placed so as to ensure a continuous cold field sufficient to ensure complete destruction of tissues within a target volume, while minimizing damage to tissues outside said target volume.

110. A method for facilitating a cryosurgery ablation procedure, comprising:

- (a) utilizing a first imaging modality for creating digitized preparatory images of an intervention site;
- (b) utilizing a three-dimensional modeler for creating a first three-dimensional model of said intervention site based on said digitized preparatory images;
- (c) utilizing a second imaging modality for creating a digitized real-time image of at least a portion of said intervention site during a cryosurgery procedure; and
- (d) utilizing an images integrator for integrating information from said three-dimensional model of said site and from said real-time image of said site in a common coordinate system, thereby producing an integrated image said site, facilitative to an operator practicing a cryoablation procedure .

111. The method of claim 110, further comprising utilizing a planning method according to claim 77.

112. The method of claim 110, further comprising utilizing a displayer for displaying said integrated image in a common virtual space.

85

113. The method of claim 112, wherein said displayed integrated image is a two-dimensional image.

114. The method of claim 112, wherein said displayed integrated image is a three-dimensional image.

115. The method of claim 110, further comprising utilizing a three-dimensional modeler for creating a second three-dimensional model of at least a portion of said intervention site based on a plurality of real-time images.

116. The method of claim 115, further comprising utilizing said images integrator to integrate information from said first three-dimensional model of said site and from said second three-dimensional model of at least a portion of said site in a common coordinate system.

117. The method of claim 110, wherein said first imaging modality comprises at least one of a group comprising magnetic resonance imaging, ultrasound imaging, and computerized tomography imaging.

118. The method of claim 110, wherein said second imaging modality comprises at least one of a group comprising magnetic resonance imaging, ultrasound imaging, and computerized tomography imaging.

119. The method of claim 118, further comprising utilizing an imaging tool to report a position of said tool during creation of said real-time image, thereby providing localizing information about said real-time image useable by said images integrator.

86

120. The method of claim 119, wherein said imaging tool is an ultrasound probe inserted in the rectum of a patient operated to report a distance of penetration of said tool in the rectum of the patient during creation of ultrasound images of a prostate of the patient.

121. The method of claim 110, wherein said first three-dimensional model is expressed in a three-dimensional Cartesian coordinate system.

122. The method of claim 112, further comprising utilizing an interface to highlight selected regions within said first three-dimensional model.

123. The method of claim 112, wherein said integrated image comprises a display of an operator-highlighted region.

124. The method of claim 112, further comprising utilizing said interface for identifying tissues to be cryoablated.

Stopped
125. The method of claim 124, wherein said integrated image further comprises a display of said operator-identified tissues to be cryoablated.

126. The method of claim 112, further comprising utilizing said interface for identifying tissues to be protected from damage during cryoablation.

127. The method of claim 124, wherein said integrated image further comprises a display of said operator-identified tissues to be protected from damage during said cryoablation.

87

128. The method of claim 122, further comprising utilizing said interface for labeling topographic features of said first three-dimensional model.

129. The method of claim 122, further comprising utilizing said interface for labeling topographic features of said real-time images.

130. The method of claim 122, further comprising utilizing said interface for labeling topographic features of said second three-dimensional model.

131. The method of claim of claim 122, wherein said images integrator matches operator-labeled topographic features of said first three-dimensional model with operator-labeled features of said real-time images, to orient said first three-dimensional model and said real-time image with respect to said common coordinate system.

132. The method of claim of claim 115, wherein said images integrator matches operator-labeled topographic features of said first three-dimensional model with operator-labeled features of said second three-dimensional model, to orient said first three-dimensional model and second three-dimensional model with respect to said common coordinate system.

133. The method of claim 112, further comprising simulating a cryosurgical intervention by utilizing a simulator having an interface, and utilizing said interface during a planning phase of said intervention to specify loci for insertion of cryoprobes into a cryoablation site in a patient and to specify operational parameters for operation of said cryoprobes for cryoablating tissues, and further utilizing said image integrator to integrate

10094784-023401

88

said specified loci into said integrated image, and utilizing said displayer to display said integrated image.

134. The method of claim 112, further comprising simulating a cryosurgical intervention by receiving from an operator during a planning phase of said intervention specifications of loci for insertion of cryoprobes into a cryoablation site and operational parameters for operation of said cryoprobes for cryoablating tissues, utilizing said image integrator to integrate said operator-specified loci into said integrated image, and utilizing said displayer to display said integrated image.

135. The method of claim 112, further comprising utilizing a first comparator for comparing said first three-dimensional model with said real-time image to determine differences.

136. The method of claim 133, further comprising utilizing apparatus for providing feedback to an operator regarding position of tools being used during a surgical intervention as compared to said loci for insertion of cryoprobes specified by an operator during said planning phase of said intervention.

137. The method of claim 133, further comprising providing feedback to an operator regarding a position of a tool being used during a surgical intervention as compared to said loci for insertion of cryoprobes specified by an operator during said planning phase of said intervention.

138. The method of claim 110, further comprising utilizing apparatus for providing feedback to an operator regarding a position of a tool being used during a surgical intervention as compared to a position of operator-identified tissues to be cryoablated.

2001 JUL 31 16:15

139. The method of claim 110, further comprising utilizing apparatus for providing feedback to an operator regarding a position of a tool being used during a surgical intervention as compared to a position of operator-identified tissues to be protected during cryoablation.

140. The method of claim 133, further comprising utilizing apparatus for guiding an operator in the placement of cryoprobes for affecting cryoablation, said guiding being according to said loci for insertion of cryoprobes specified by an operating during said planning phase of said intervention.

141. The method of claim 133, further comprising guiding an operator in the placement of cryoprobes for affecting cryoablation, said guiding being according to said loci for insertion of cryoprobes specified by an operating during said planning phase of said intervention.

142. The method of claim 133, further comprising utilizing apparatus for limiting movement of a cryoprobe during a cryoablation intervention, said limitation being according to said loci for insertion of cryoprobes specified by an operating during said planning phase of said intervention.

143. The method of claim 133, further comprising utilizing cryoprobe displacement apparatus for moving at least one cryoprobe to at least one of said loci for insertion of cryoprobes specified by an operator during said planning phase of said intervention.

144. The method of claim 143, further comprising utilizing a stepper motor to move said cryoprobe.

00917841-02310
-T0F020-T0F020-

90

145. The method of claim 143, further comprising utilizing a position sensor to sense a position of said cryoprobe.

146. The method of claim 143, further comprising utilizing control apparatus to control cooling of said at least one cryoprobe.

147. The method of claim 143, further comprising utilizing control apparatus to control heating of said at least one cryoprobe.

148. The method of claim 146, further comprising controlling said at least one cryoprobe according to a schedule of movements coordinated with a schedule of alternative heating and cooling of said at least one cryoprobe, to affect cryoablation at a plurality of loci.

401220-182660